DEC 2 9 2011

Special 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: December 5th, 2011

1. Company sponsoring this submission:

Name –Rayence Co., Ltd.
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445-170, Korea
Telephone – +82-31-8015-6459
Fax – +82-31-8015-6598
Contact – Kee Dock Kim / Manager
Internet – http://www.rayence.com

2. Official correspondent (U.S. Designated agent)

Mtech Group
12946 Kimberley Ln Houston, TX 77079
Tel: +713-467-2607
Fax: +713-464-8880
Contact person: Mr. Dave Kim
Email: davekim@mtech-inc.net

3. Device :

Trade/proprietary name	: 1210SGA
Common Name	: Digital Flat Panel X-ray Detector
Classification Name	: Solid State X-ray Imaging Device

4. Predicate Device :

Manufacturer	: Rayence Co., Ltd.
Device	: Xmaru1210P
510(k) Number	: K101590 (Decision Date - Nov. 29th, 2010)

5. Classifications Names & Citations :

21CFR 892.1650, MQB, Solid State X-ray Imaging Device, Class2

6. Description :

6.1 General

1210SGA is a digital solid state X-ray detector that is based on flat-panel technology. This radiographic image detector and processing unit consists of a scintillator coupled to an a-Si TFT sensor. This device needs to be integrated with a radiographic imaging system. It can be utilized to capture and digitalize X-ray images for radiographic diagnosis The RAW files can be further processed as DICOM compatible image files by separate console SW (not part of this 510K submission) for a radiographic diagnosis and analysis.

7. Indication for use :

1210SGA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, spinal column, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health professionals. Not to be used for mammography.

8. Comparison with predicate device :

Rayence Co., Ltd. believes that 1210SGA is substantially equivalent in comparison with Xmaru1210P of Rayence Co., Ltd.

9. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Rayence Co., Ltd. concludes that 1210SGA is safe and effective and substantially equivalent in comparison with the predicate device as described

herein.

10. Rayence Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Rayence Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
12946 Kimberly Lane
HOUSTON TX 77079

AUG 23 2013

Re: K113630
Trade/Device Name: Digital Flat Panel X-Ray Detector/1210SGA
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 5, 2011
Received: December 8, 2011

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of December 29, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K113630

Device Name: Digital Flat Panel X-Ray Detector /1210SGA

Indications for Use:

1210SGA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck. spinal column, arm. leg and peripheral (foot. hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health professionals. Not to be used for mammography.

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Mary S Pastel

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113630